



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,312	03/25/2004	Takafumi Ueno	1011350-000332	5636

  

21839	7590	12/17/2010
BUCHANAN, INGERSOLL & ROONEY PC		
POST OFFICE BOX 1404		
ALEXANDRIA, VA 22313-1404		

  

EXAMINER	
FLICK, JASON E	

  

ART UNIT	PAPER NUMBER
3763	

  

NOTIFICATION DATE	DELIVERY MODE
12/17/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com  
offserv@bipc.com

**Supplemental  
Notice of Allowability**

Application No.

10/808,312

Examiner

JASON FLICK

Applicant(s)

UENO ET AL.

Art Unit

3763

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communication filed 11/15/2010.
2. ☒ The allowed claim(s) is/are 1-7 and 9-19.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 11/15/10
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_.

/JASON FLICK/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

## **DETAILED ACTION**

### **Information Disclosure Statement**

1. The information disclosure statement (IDS) submitted on 11/15/2010 was filed after the mailing date of the Notice of Allowance on 10/01/2010. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### **EXAMINER'S AMENDMENT**

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Wendi Weinstein on 09/21/2010.

The application has been amended as follows:

**Previously withdrawn claim 18 has now been rejoined.**

### **REASONS FOR ALLOWANCE**

3. Claims 1-7 and 9-19 are allowed over the prior art of record as amended by the applicant on 09/10/2010 and as amended above.

Art Unit: 3763

4. The following is an examiner's statement of reasons for allowance: The claims in this application have been allowed because the prior art of record fails to disclose or render obvious the structure and method as recited in independent claims 1, 12, and 15.

5. The closest prior art of record is Eggers et al. (USPN 6,106,524); Haim et al. (USPN 6,309,370); and Shapland et al. (WO 9904851 A1).

6. Regarding independent claims 1, 12, and 15, the closest prior art of record fails to teach among all the limitations or render obvious a structure and method comprising a method of injecting a therapeutic composition by use of a catheter to be percutaneously inserted into a living body lumen, said catheter comprising a sheath portion having a lumen extending therein, an insertion member slidably disposed in said lumen of said sheath portion and having a distal end portion capable of protruding from a distal end portion of said sheath portion, an injection needle disposed at said distal end portion of said insertion member for injecting said therapeutic composition into a target tissue, and a first electrode, separate and distinct from both said insertion member and said injection needle, said first electrode being fixedly secured to an external surface of said distal end portion of said insertion member and spaced a predetermined distance from a bevel of said injection needle for measuring a cardiac action potential, said method comprising the steps of: inserting said catheter into a living body and advancing said catheter to the vicinity of said target tissue; and puncturing said target tissue by said injection needle and injecting said therapeutic composition into said target tissue through said injection needle, based on said cardiac action potential

Art Unit: 3763

measured by said first electrode spaced the predetermined distance from a bevel of said injection needle.

### ***Conclusion***

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON FLICK whose telephone number is (571)270-7024. The examiner can normally be reached on Monday through Thursday, 7:00am to 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F./

Examiner, Art Unit 3763

11/24/2010